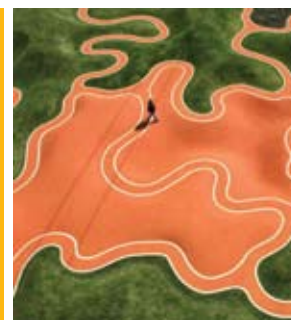


IDRAC[®] MEDICAL DEVICE COVERAGE

AUTHORITATIVE, GLOBAL REGULATORY REQUIREMENTS ON MEDICAL DEVICES



WHAT YOU CAN DO

- Access key explanatory documents
- Speed up access to the information you need
- Track changes to documents
- Trace each step of new regulations
- Browse easily between documents
- Receive configurable email alerts
- Facilitate better collaboration

WHEN YOU CAN BENEFIT

- Planning clinical trials
- Product registration and commercialization
- Market optimization

UNSURPASSED DEPTH OF COVERAGE

IDRAC[®] from Thomson Reuters brings together everything you need to keep up with the ever-changing regulatory requirements for medical devices in key countries and regions around the world, replacing the onerous and time-consuming tasks of acquiring, compiling, indexing, cross-referencing, updating and analyzing this information.

For each country or region, its documents are thematically organized for easy retrieval, with more added every day.

- **Reference texts**, normally in the local language (with complementary translations into English for China, Japan and South Korea)
- **Unique explanatory documents** written in English by our team of experts to explain key processes and trends in each country

A powerful search engine enables you to interrogate the entire database in seconds using full text, title, and keyword searches.

OUTSTANDING FLEXIBILITY AND SERVICE

You can build the coverage that suits you by subscribing only to the countries relevant to your organization.

As standard, every *IDRAC* subscription also includes free access to an extensive library of reference texts and explanatory documents covering international organizations such as ICH, WHO, PIC/S, and many others.

IDRAC is supported by a team of global regulatory affairs professionals and database management and online development experts. Training is provided by qualified instructors who can visit your site at your convenience or host a virtual training session online.

You will also receive comprehensive customer service through easy-to-follow product manuals, dedicated telephone and email helpdesk support and our regular *IDRAC Weekly Alert*.

AVAILABLE MODULES

- Australia
- Canada
- China
- Europe
- France
- Germany
- India
- Japan
- The Netherlands
- South Korea
- UK
- US



EU MODULE

Reference texts cover:

- The Medical Device Directive
- The Active Implantable Medical Devices Directive
- The In Vitro Diagnostics Directive
- MEDDEV guidelines

The module also contains information on other directives such as the EU Waste Electrical and Electronic Equipment Directive 2002/96/EC, Directive 2005/50/EC on Reclassification of Hip, Knee and Shoulder Joint Replacements, and Directive 2003/32/EC for Devices Manufactured Utilising Tissues of Animal Origin.

Expert Reports cover:

- How to market medical devices
 - Definition
 - Legal framework including European Directives, Classification, Essential Requirements, Competent Authorities, Notified Bodies
 - Requirements for design and compliance including Preclinical Assessment
 - Clinical evaluation
 - Labeling requirements, including CE marking
 - Post-marketing requirements
 - Fees
 - Pricing and reimbursement
 - Advertising
 - International aspects (GHTF, GMDN, MRAs)
 - A brief overview of human tissue engineered products
 - REACH
 - Checklists for essential requirements and technical file
- How to market combination products
- How to market advanced therapy products

US MODULE

Reference texts cover:

- Major acts within the scope of *IDRAC*, including Medical Device User Fee and Modernization Act (MDUFMA) and the Food and Drug Administration Amendments Act of 2007
- Code of Federal Regulations 21 CFR Parts 800 to 898 (2005–present) – CFR is updated in blue text as Final Rules become effective and the amended text remains in blue for one year
- Federal Register – all proposed and final rules affecting the CFR, including the Center for Devices and Radiological Health (CDRH) guidances
- CDRH guidances (2005–present) related to therapeutic use.
- EIRs, FDA 483 and Correspondence, FDA Enforcement Reports
- Major EIRs dealing with medical devices (since June 2002)

Major forms likely to be used by regulatory affairs departments in medical device companies are provided in ready-to-use Microsoft® Word format.

Expert Reports cover:

- How to market medical devices
 - Definition
 - Legal framework
 - Requirements for registration format and content of applications
 - Fees
 - Clinical research
 - Labeling requirements
 - Post-marketing requirements
 - Pricing and reimbursement
 - Advertising
 - Federal pre-emption
 - International aspects
- How to market combination products
- How to market advanced therapy products

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